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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,352	BRAUN ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-22* is/are pending in the application.

4a) Of the above claim(s) *3,5,8,9 and 12-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,7,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on April 6, 2009 is acknowledged. Claims 1 and 3-22 are pending. Claims 1, 3, and 4 have been amended. Claim 2 has been canceled. Claims 3, 5, 8, 9 and 12-22 were previously withdrawn. Claims 1, 4, 6, 7, 10 and 11 are under examination.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on August 15, 2008 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

Objections Withdrawn

2. In view of Applicant's amendment, the objection to claim 1 because claim 1 recites language drawn to non-elected inventions is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 1, 4, 6, 7, 10, and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for the

reasons set forth in the previous office action. The cancellation of claim 2 renders the rejection of said claim moot.

Applicant argues that:

1) The Examiner states that the claims are broadly drawn, however, the claims are directed specifically to the treatment or prevention of diseases due to infection by *Neisseria meningitidis*.

2) The selection of oligosaccharides of LOS with the concrete cross-reactivity renders claim 1 very specific, because only some *Moraxella catarrhalis* strains have LOS oligosaccharides which are cross-reactive with *Neisseria meningitidis* and human blood group antigens.

3) The application provides sufficient information to people with ordinary skill in the art on how to obtain these LOS from *Moraxella catarrhalis.*

4) Applicants would like to point out that HIV-disease and gonococcal disease have totally different pathogenic mechanisms compared to meningococcal disease.

5) People with ordinary skill in the art would appreciate that the vaccine induces anti-inflammatory, neutralizing, bactericidal and opsonising antibodies and therefore would understand that the antibodies are powerful vaccines.

6) The experiments provide substantive evidence that the vaccine of the present application is immunogenic and not harmful.

7) The working examples are highly relevant because the interactions shown are the relevant molecular interactions in the treatment of meningococcal disease.

Applicant's arguments have been considered and are deemed non-persuasive.

With regard to Points 1, 2 and 5, while the claims have been amended to specifically treat or prevent diseases due to infection by *Neisseria meningitidis* and recite a specific selection of oligosaccharides of LOS, the claims remain broad in the sense that they are drawn to a medicament for the prevention of diseases due to infection by *Neisseria meningitidis,* characterized in that it comprises lipooligosaccharides purified from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens. Applicants have failed to point out and/or distinctly claim what is enabled. To be a prophylactic medicament, said medicament must induce a protective immune response demonstrated by challenge experiments in an acceptable animal model. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity against infection by *Neisseria meningitidis.* This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing a condition. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced.

Moreover, the instant specification discloses the binding of antibodies to blood group antigens by *Moraxella catarrhalis* isolates (see pages 37-38), the ability to induce lower cytokine levels (see page 53), the binding of antibodies to blood group antigens

and meningococcal immune type antibodies by *Moraxella catarrhalis* strains from adults and children (see page 52), anti-LOS antibodies from *Moraxella catarrhalis*, which were bactericidal, opsonophagocytic and anti-inflammatory, while those same anti-LOS antibodies were not for human serum absorbed with *Moraxella catarrhalis* (see pages 54-55; Tables 15 and 19). However binding of antibodies and ability to induce lower cytokine levels does not necessarily correlate to protective immunity. The specification does not provide a demonstration where a pathogen free subject was administered the claimed composition and as a result the subject was protected from a given pathogen or condition due to infection by *Neisseria meningitidis*.

Further, a medicament with anti-inflammatory, neutralizing, bactericidal and opsonising antibodies does not necessarily correlate to having preventive abilities or a powerful vaccine.

With regard to Point 3, the claims are drawn to a medicament for the prevention of diseases due to infection by *Neisseria meningitidis*, characterized in that it comprises lipooligosaccharides purified from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens. Moreover, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., how to obtain these LOS from *Moraxella catarrhalis*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to Point 4, the Examiner concedes that HIV-disease and gonococcal disease have totally different pathogenic mechanisms compared to meningococcal disease, however, the analogy was used to demonstrate that HIV, for example, induces the production of neutralizing antibodies but to date, there is no effective HIV-1 vaccine. Further promoting that the production of antibodies is not necessarily correlated to protection or prevention of a disease.

With regard to Point 6, the Examiner does not negate that the medicament is immunogenic and not harmful. The specification does not provide a working example in which a patient is subjected to immunization with said medicament. To be a prophylactic medicament, said medicament must induce a protective immune response demonstrated by challenge experiments in an acceptable animal model. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity against infection by *Neisseria meningitidis*. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing a condition.

With regard to Point 7, there are no working examples, which suggest a method of preventing an infection by *Neisseria meningitidis* comprising any purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B, or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are

oligosaccharides of LOS, which are cross-reactive with human blood group antigens. Moreover, the specification is silent with regard to where an *in vivo* demonstration is located. The claimed invention is drawn to an *in vivo* medicament for the treatment or prevention of diseases due to *Neisseria meningitidis* for this reason an *in vivo* demonstration must be provided.

As previously presented, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the

establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to a medicament for the prevention of diseases due to infection by *Neisseria meningitidis*, characterized in that it comprises lipooligosaccharides purified from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

Breadth of the claims: The claims are broadly drawn and encompass a medicament for the treatment or prevention of any disease due to infection by *Neisseria meningitidis*, characterized in that it comprises any purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

Direction or guidance presented in the specification: The instant claims are drawn to a medicament for the treatment or prevention of any disease due to infection by *Neisseria meningitidis* comprising any purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens. To be a prophylactic medicament, said medicament must induce a protective immune response demonstrated by challenge experiments in an acceptable animal model. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity against infection by *Neisseria meningitidis*. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing a condition. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced. The instant specification discloses the binding of antibodies to blood group antigens by *Moraxella catarrhalis* isolates (see pages 37-38), the ability to induce lower cytokine levels (see page 53), the binding of antibodies to blood group antigens and meningococcal immune type antibodies by *Moraxella catarrhalis* strains from adults and children (see page 52), anti-LOS antibodies from *Moraxella catarrhalis*, which were bactericidal, opsonophagocytic and anti-inflammatory, while those same anti-LOS antibodies were not for human serum absorbed with *Moraxella catarrhalis* (see pages

54-55; Tables 15 and 19). However binding of antibodies and ability to induce lower cytokine levels does not necessarily correlate to protective immunity. For example, HIV-1 induces the production of neutralizing antibodies but to date, there is no effective HIV-1 vaccine. The specification does not provide a demonstration where a pathogen free subject was administered the claimed composition and as a result the subject was protected from a given pathogen or condition due to infection by *Neisseria meningitidis*.

The specification, however, does not disclose treatment and/or prevention of a representative number of members of the genus to which the claims are drawn, such as the condition being treated or prevented, the nature of the LOS, which eptiopes on the LOS are required and induce antibodies that are cross-reactive with serogroup B, the structure of the epitopes; or how the epitopes can be derived. Moreover, the specification does not disclose distinguishing and identifying features of a representative number of members of the genus to which the claims are drawn (i.e. which purified lipooligosaccharides are required to induce the recited cross-reactive antigens to *Neisseria meningitidis* of serogroup B) so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus. Therefore the specification fails to adequately describe at least a substantial number of members of the genus to which the claims are based.

There is insufficient direction or guidance presented in the specification with regard to the prevention of any condition, particularly the prevention of a condition due to infection by *Neisseria meningitidis*. The demonstration of treating and/or preventing any condition due to infection by *Neisseria meningitidis* is required for the skilled artisan

to be able to use the claimed method for their intended purpose. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of following the claimed method steps.

Presence or absence of working examples: There are no working examples, which suggest a method of treating and/or preventing (prophylaxis) any condition due to infection by *Neisseria meningitidis* comprising any purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

State of the prior art: The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

Moreover, Greenspan et al. (Nature Biotechnology 17: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding.

Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other.

Quantity of experimentation necessary: The quantity of experimentation necessary would be undue. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of

guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

4. The rejection of claims 1, 4, 6, 7, 10, and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons set forth in the previous office action. The cancellation of claim 2 renders the rejection of said claim moot.

Applicant argues that:

1) The scope of the claims is not overly broad, because the definition of the LOS is very specific.

Applicant's arguments have been considered and are deemed non-persuasive.

With regard to Point 1, contrary to Applicant's assertion the claims are not specific in that they do not describe the genus of LOS. To adequately describe the genus of LOS, Applicant must adequately describe the purified lipooligosaccharides from commensal *Moraxella catarrhalis* that has the distinct capability to be cross-reactive with antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

As previously presented, the claims are broadly drawn and encompass a medicament for the treatment or prevention of diseases due to infection by *Neisseria*

meningitidis, characterized in that it comprises purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

Moreover, the instant claims encompass a medicament for the treatment or prevention of any disease due to infection by *Neisseria meningitidis* comprising any purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B.

Moreover, the claims require the use of purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B that are not defined (i.e. they do not have possession of the LOS).

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention. To adequately describe the genus of LOS, Applicant must adequately describe the purified lipooligosaccharides from commensal *Moraxella catarrhalis* that has the distinct capability to be cross-reactive with antigens to *Neisseria meningitidis* of

the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

The specification, however, does not disclose treatment and/or prevention of a representative number of members of the genus to which the claims are drawn, such as the condition being treated or prevented, the nature of the LOS, which eptiopes on the LOS are required and recognized against serogroup B, the structure of the epitopes; how the epitopes can be derived, so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus. Therefore the specification fails to adequately describe at least a substantial number of members of the genus to which the claims are based.

Moreover, Greenspan et al. (Nature Biotechnology 17: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine whether an antibody binds the same epitope as another antibody because an antibody

that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other.

A representative number of species means that the species that are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus.

See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.
The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by

disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the Applicant had possession of the claimed invention at the time the instant application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The rejection of claims 1, 4, 6, 7, 10, and 11 under 35 U.S.C. 102(e) as being anticipated by Gu et al. (U.S. Patent 6,685,949 B1) is maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) Gu et al. do not teach or suggest a selection for cross-reactivity.

2) In meningococcal disease, serogroup A strains of *Moraxella catarrhalis* are not cross-reactive with *Neisseria meningitidis* LOS as well as human blood group antigens.

Applicant's arguments have been considered and are deemed non-persuasive.

The rejected claims are drawn to a medicament for the treatment or prevention of diseases due to infection by *Neisseria meningitidis*, characterized in that it comprises purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B or antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are oligosaccharides of LOS, which are cross-reactive with human blood group antigens.

With regard to Point 1, the claimed medicament is identical to that of Gu et al. and necessarily encompasses a selection for cross-reactivity.

With regard to Point 2, Applicant is reminded that the claims recite purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* with cross-reactive antigens to *Neisseria meningitidis* of the serogroup B *or* antibodies against such lipoligosaccharides wherein the cross-reactive antigens to *Neisseria meningitidis* are

oligosaccharides of LOS, which are cross-reactive with human blood group antigens. Consequently, the purified lipooligosaccharides (LOS) from commensal *Moraxella catarrhalis* of Gu et al. are necessarily cross-reactive antigens to *Neisseria meningitidis* of the serogroup B.

As previously presented, Gu et al. disclose a vaccine comprising lipooligosaccharides isolated from *M. catarrhalis*. Gu et al. disclose that the LOS can be treated (detoxified) to remove esterified fatty acids or to remove lipid A to produce an oligosaccharide (see column 3, lines 42-48). Gu et al. disclose that in one embodiment, the fatty acids are removed with hydrazine or a mild alkaline reagent (see column 4, lines 52-53). Gu et al. disclose that the invention is a pharmaceutical composition that includes a vaccine conjugate in a pharmaceutically acceptable carrier, which may include an adjuvant (column 3, lines 64-66). Moreover, Gu et al. disclose that for vaccination, the vaccine can be administered transmucosal (i.e. intranasally). For intranasal administration, the formulation may be aerosolized (see column 14, lines 1-5 and 22-25).

The composition of Gu et al. is the same as the instantly claimed medicament. The LOS from *Moraxella catarrhalis* necessarily has antigens that are cross-reactive to *Neisseria meningitidis* of the serogroup B.

Claim limitations such as "for the treatment or prevention of diseases due to infection by *Neisseria meningitidis* " are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
4/24/09

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645